K082271

OCT 0 6 2008

510(k) SUMMARY

SUBMITTED BY:

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
Phone 410-316-4938
Fax: 410-316-4499

CONTACT NAME: Janine Matlak, Regulatory Affairs Specialist

DATE PREPARED: August 8, 2008

DEVICE TRADE NAME: Fluconazole 25µg, BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks

DEVICE COMMON NAME: Antimicrobial Susceptibility Test Disks

DEVICE CLASSIFICATION: 21 CFR§866.1620, Class II (Product Code JTN), Susceptibility Test Disks, Antimicrobial

PREDICATE DEVICE: Other BBL™ Sensi-Disc™
(eg, Ciprofloxacin 5 µg, BBL™ Sensi-Disc™)

INTENDED USE:

Antimicrobial Susceptibility Test Disks are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Fluconazole 25µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Fluconazole of a wide range of pathogens, as described in the "Indications for Use" section. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer and received FDA approval under NDA Number 19-949.

510(k) SUMMARY

Indications for Use:

Use of Fluconazole 25µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of pathogens to Fluconazole. The concentration of 25µg has been shown to be active *in vitro* against most strains of *Candida* species listed below, as described in the FDA approved drug insert for this agent.

Active *In Vitro* and in Clinical Infections Against:

Candida albicans
Candida glabrata (Many strains are intermediately susceptible)
Candida parapsilosis
Candida tropicalis

Active *In Vitro* Against:

Candida dubliniensis
Candida guilliermondii
Candida kefyr
Candida lusitaniae

DEVICE DESCRIPTION:

Fluconazole 25µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Fluconazole supplied by the drug manufacturer. Each Fluconazole disk is clearly marked on both sides with the agent and drug content. Fluconazole cartridges each contain 50 impregnated disks that are packed as either a single cartridge in a single box, or in a package containing ten cartridges. Fluconazole disks are used for semi-quantitative *in vitro* susceptibility evaluations by the agar diffusion test method.

Agar diffusion susceptibility methods employing dried filter paper disks impregnated with specific concentrations of antimicrobial agents were developed in the 1940s. In order to eliminate or minimize variability in the testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.
Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the Clinical and Laboratory Standards Institute (CLSI) [Formerly National Committee for Clinical Laboratory Standards (NCCLS)] and is periodically updated.

DEVICE PRINCIPLE:

Disks containing a wide variety of selected agents are applied to the surface of Mueller Hinton Agar plates, supplemented as needed and inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the disks are measured and compared with established zone size ranges for individual agents in order to determine the agent(s) most suitable for use in therapy. The categorical interpretation [susceptible (S), susceptible-dose dependent (S-DD), or resistant (R)] for the organism being tested is made by comparing zone diameters to those found in the approved pharmaceutical package insert.

DEVICE COMPARISON:

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks – Fluconazole 25µg is similar to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- Both methods are for susceptibility testing using paper disks impregnated with an agent.
- Both methods are intended to test susceptibility to pathogenic isolates.
- Both methods provide the user with minimum inhibitory concentration (MIC) results based on measurements of zone diameters.
- Both methods require the user to determine categorical interpretations using the measured zone diameters against CLSI Approved Standards.
- Both methods use pure cultures of isolates.

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Fluconazole 25µg differs from the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Fluconazole 25µg is a susceptibility test that uses disks impregnated with Fluconazole at a concentration of 25µg while the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg is a susceptibility test that uses disks impregnated with Ciprofloxacin at a concentration of 5 µg.
- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk – Fluconazole 25 µg is a susceptibility test used to test a different battery of isolates than the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Ciprofloxacin 5 µg.

SUBSTANTIAL EQUIVALENCE TESTING DATA:

See the Fluconazole drug package insert, "Susceptibility Testing Methods: Diffusion Techniques" (Appendix 1).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 0 6 2008

Ms. Janine Matlak
Regulatory Affairs Specialist
BD Diagnostics Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: k082271
Trade/Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Disks, Fluconazole 25 µg
Regulation Number: 21 CFR 866.1620
Regulation Name: Antimicrobial Susceptibility Test Disc
Regulatory Class: Class II
Product Code: JTN
Dated: August 8, 2008
Received: August 11, 2008

Dear Ms. Matlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

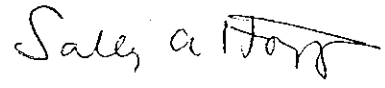
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082271

Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Fluconazole25µg

Indications for Use:

Use of Fluconazole 25µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of pathogens to Fluconazole. The concentration of 25µg has been shown to be active *in vitro* against most strains of *Candida* species listed below, as described in the FDA approved drug insert for this agent.

Active *In Vitro* and in Clinical Infections Against:

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Candida parapsilosis
Candida tropicalis

Active *In Vitro* Against:

Candida dubliniensis
Candida guilliermondii
Candida kefyr
Candida lusitaniae

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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